PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference 40738WOP00	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/AU2004/001438	International filing date *(day/month/year)* 20 October 2004	Priority date *(day/month/year)* 24 October 2003

International Patent Classification (IPC) or national classification and IPC

Int. Cl. ***A01N 25/08*** (2006.01) ***A01N 63/00*** (2006.01) ***C02F 1/50*** (2006.01)
A01N 25/34 (2006.01) ***A61L 2/23*** (2006.01) ***C11D 7/42*** (2006.01)

Applicant

NOVAPHARM RESEARCH (AUSTRALIA) PTY LTD et al

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. [X] *(sent to the applicant and to the International Bureau)* a total of 5 sheets, as follows:
      - [ ] sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      - [ ] sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. [ ] *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
   - [X] Box No. I Basis of the report
   - [ ] Box No. II Priority
   - [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - [ ] Box No. IV Lack of unity of invention
   - [X] Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - [ ] Box No. VI Certain documents cited
   - [ ] Box No. VII Certain defects in the international application
   - [ ] Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
15 August 2005	16 February 2006
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer **GAYE HOROBIN** Telephone No. (02) 6283 2069

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2004/001438

Box No. I Basis of the report

1. With regard to the language, this report is based on:

[X] The international application in the language in which it was filed

[ ] A translation of the international application into , which is the language of a translation furnished for the purposes of:

[ ] international search (under Rules 12.3(a) and 23.1 (b))

[ ] publication of the international application (under Rule 12.4(a))

[ ] international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

[ ] the international application as originally filed/furnished

[X] the description:

pages **1,3-8** as originally filed/furnished
pages* received by this Authority on with the letter of
pages* **2** received by this Authority on **15 August 2005** with the letter of **15 August 2005**

[X] the claims:

pages as originally filed/furnished
pages* as amended (together with any statement) under Article 19
pages* **10-12** received by this Authority on **15 August 2005** with the letter of **15 August 2005**
pages* **9** received by this Authority on **23 January 2006** with the letter of **23 January 2006**

[ ] the drawings:

pages as originally filed/furnished
pages* received by this Authority on with the letter of
pages* received by this Authority on with the letter of

[ ] a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. [ ] The amendments have resulted in the cancellation of:

[ ] the description, pages
[ ] the claims, Nos.
[ ] the drawings, sheets/figs
[ ] the sequence listing *(specify)*:
[ ] any table(s) related to the sequence listing *(specify)*:

4. [ ] This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

[ ] the description, pages
[ ] the claims, Nos.
[ ] the drawings, sheets/figs
[ ] the sequence listing *(specify)*:
[ ] any table(s) related to the sequence listing *(specify)*:

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-28	YES
	Claims		NO
Inventive step (IS)	Claims	1-28	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-28	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

NOVELTY(N), INVENTIVE STEP(IS)

No citation or obvious combination of citations discloses all of the features of the claimed invention. The nearest art is considered to be EP 619 367 which does not specifically disclose the presence of an excipient selected so that the tablet will not fully dissolve in water at ambient temperature for a period of at least three months.

between the bottom of the coils and the drip tray is normally too limited to allow clear access.

In commercial air conditioning systems, drip trays are usually located in an air treatment plant of the building – an area with restricted access. Often the trays are positioned at a height of up to 5m, requiring use of a ladder, and their servicing is done by highly qualified technicians, i.e. expensive and time-consuming. It is not uncommon to find a tray that is serviced once every 12-24 months, if at all.

Any discussion of the prior art throughout the specification should in no way be considered as an admission that such prior art is widely known or forms part of common general knowledge in the field.

It is an object of preferred embodiments of the present invention to provide an improved method for controlling biofilm in a drip tray and its drainage line or the like, and to provide a tablet for use in the method, and a method of manufacture of such tablets.

Brief statement of the invention

The present inventors have conceived the idea of incorporating an enzyme in a drip tray tablet containing a biocide. This has been found not merely to kill microorganisms, but also to remove biofilm and prevent biofilm drain blockage.

According to a first aspect the invention provides a tablet for use in a drip tray, the tablet including:

an excipient selected so that the tablet will not fully dissolve in water at ambient temperature for a period of at least one month;

at least 500 ppm of a biocide;

at least one enzyme; and

enzyme preserving means for maintaining enzyme activity in a moist environment.

By "slowly soluble" is meant an excipient such that the tablet will not fully dissolve in water at ambient temperature for a period of at least one month, and preferably, will not fully dissolve for a period of more than 6 months, or even more preferably, will not fully dissolve for a period of more than 12 months. In other preferred embodiments, the tablet will not fully dissolve in water at ambient temperature for a

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:-

1. A tablet for use in a drip tray, the tablet including:

   an excipient selected so that the tablet will not fully dissolve in water at ambient temperature for a period of at least one month;

   at least 500 ppm of a biocide;

   at least one enzyme; and

   enzyme preserving means for maintaining enzyme activity in a moist environment.

2. A tablet according to claim 1 wherein the excipient is selected such that the tablet will not fully dissolve in water at ambient temperature for a period of at least 6 months.

3. A tablet according to claim 1 wherein the excipient is selected such that the tablet will not fully dissolve in water at ambient temperature for a period of at least 12 months.

4. A tablet according to any one of the preceding claims wherein the excipient includes one or more compounds selected from the group consisting of poly vinyl alcohols, high molecular weight polyethylene glycols, high molecular weight polypropylene glycols, esters or partial esters of polyethylene glycols or of polypropylene glycols, and high molecular weight thermoplastic surfactants.

5. A tablet according to claim 4 wherein the excipient includes one or more high molecular weight thermoplastic surfactants compounds selected from the group consisting of polyoxyethylene condensates, polyoxypropylene condensates, polyoxyethylene-polyoxypropylene copolymers with appropriate hydrophobes, and combinations thereof.

6. A tablet according to any one of the preceding claims wherein the at least one enzyme is selected from the group consisting of proteolytic and hydrolase enzymes.

7. A tablet according to any one of the preceding claims wherein the enzyme preserving means includes a boron compound.

8. A tablet according to claim 7 wherein the boron compound is present in a concentration sufficient to maintain enzyme activity for at least three months during use.

9. A tablet according to any one of the preceding claims wherein the excipient comprises 2% to 95% by weight of the tablet.

10. A tablet according to any one of the preceding claims wherein the excipient comprises 10% to 80% by weight of the tablet.

11. A tablet according to any one of claims 1 to 9 wherein the excipient comprises 20% to 60% by weight of the tablet.

12. A tablet according to any one of the preceding claims wherein the at least one enzyme comprises up to 20% by weight of the tablet.

13. A tablet according to any one of the preceding claims wherein the at least one enzyme comprises up to 10% by weight of the tablet

14. A tablet according to any one of claims 1 to12 wherein the at least one enzyme comprises up to 5% by weight of the tablet.

15. A tablet according to any one of claims 1 to 12 wherein the at least one enzyme comprises up to 3% by weight of the tablet.

16. A tablet according to any one of the preceding claims wherein the enzyme preserving means is present in an amount of from 0.1% to 10% by weight of the tablet.

17. A tablet according to any one of the preceding claims wherein the enzyme preserving means is present in an amount of from 0.1% to 3% by weight of the tablet.

18. A tablet according to any one of the preceding claims wherein the biocide is present in an amount of from 0.1% to 20% by weight of the tablet

19. A tablet according to any one of the preceding claims wherein the biocide is present in an amount of from 0.5% to 10% by weight of the tablet.

20. A tablet according to any one of claims 1 to 18 wherein the biocide is present in an amount of from 1% to 5% by weight of the tablet.

21. A tablet according to any one of the preceding claims further including a surfactant.

22. A tablet according to any one of the preceding claims when made in a tablet press.

23. A tablet according to any one of the claims 1 to 21 when made by a process including the step of moulding.

24. A tablet according to any one of the claims 1 to 21 when made by a process including the step of extrusion.

25. A tablet according to any one of the claims 1 to 21 when provided with slow release encapsulation.

26. A method for inhibiting the growth of a biofilm in a drip tray or the like, including the step of adding to the tray, a tablet according to any one of the preceding claims.

27. A tablet substantially as herein described with reference to any one of the examples but excluding any comparatives.

28. A method substantially as herein described with reference to any one of the examples but excluding any comparatives.

Box No. VIII (ii) DECLARATION: ENTITLEMENT TO APPLY FOR AND BE GRANTE PCT/AU2004/001438

The declaration must conform to the standardized wording provided for in Section 212; see Notes to Boxes Nos. VIII, VIII (i) to (v) (in general) and the specific Notes to Box No. VIII (ii). If this Box is not used, this sheet should not be included in the request.

Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent (Rules 4.17(ii) and 51*bis*.1(a)(ii)), in a case where the declaration under Rule 4.17(iv) is not appropriate:

In relation to this international application,

Novapharm Research (Australia) Pty Ltd is entitled to apply for and be granted a patent by virtue of the following:

Novapharm Research (Australia) Pty Ltd, of 3-11 Primrose Avenue, Rosebery, New South Wales, 2018, Australia is entitled as employer of the inventor, Steven Kritzler of 9 Redgum Avenue, Cronulla, New South Wales, 2230, Australia

Novapharm Research (Australia) Pty Ltd, of 3-11 Primrose Avenue, Rosebery, New South Wales, 2018, Australia is entitled as employer of the inventor, Alex Sava of 3/124 Paddington Street, Paddington, New South Wales, 2021, Australia

This declaration is made for purposes of: all designations except the designation of the United States of America

☐ This declaration is continued on the following sheet, "Continuation of Box No. VIII (ii)".

Box No. VIII (iv) DECLARATION: INVENTORSHIP (only for the purposes of the designation of the United States of America)

The declaration must conform to the standardized wording provided for in Section 214; see Notes to Boxes Nos. VIII, VIII (i) to (v) (in general) and the specific Notes to Box No. VIII (iv). If this Box is not used, this sheet should not be included in the request.

Declaration of inventorship (Rules 4.17(iv) and 51 *bis*.1(a)(iv)) for the purposes of the designation of the United States of America:

I hereby declare that I believe I am the original, first and sole (if only one inventor is listed below) or joint (if more than one inventor is listed below) inventor of the subject matter which is claimed and for which a patent is sought.

This declaration is directed to the international application of which it forms a part (if filing declaration with application).

This declaration is directed to international application No. PCT/AU2004/001438 (if furnishing declaration pursuant to Rule 26*ter*).

I hereby declare that my residence, mailing address, and citizenship are as stated next to my name.

I hereby state that I have reviewed and understand the contents of the above-identified international application, including the claims of said application. I have identified in the request of said application, in compliance with PCT Rule 4.10, any claim to foreign priority, an I have identified below, under the heading "Prior Applications," by application number, country or Member of the World Trade Organization, day, month and year of filing, any application for a patent or inventor's certificate filed in a country other than the United States of America, including any PCT international application designating at least one country other than the United States of America, having a filing date before that of the application on which foreign priority is claimed.

Prior Applications:

I hereby acknowledge the duty to disclose information that is known by me to be material to patentability as defined by 37C.F.R.§ 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the PCT international filing date of the continuation-in-part application.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief ar believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name: Steven KRITZLER

Residence: New South Wales, Australia
(city and either US state, if applicable, or country)

Mailing Address: 9 Redgum Avenue, Cronulla, New South Wales 2230, Australia

Citizenship: Australian Citizen

Inventor's Signature: _____ Date: 16/2/05
(if not contained in the request, or if declaration is corrected or added under Rule 26*ter* after the filing of the international application. The signature must be that of the inventor, not that of the agent)

(of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26*ter* after the filing of the international application)

Name: Alex SAVA

Residence: New South Wales, Australia
(city and either US state, if applicable, or country)

Mailing Address: 3/124 Paddington Street, Paddington, New South Wales 2021, Australia

Citizenship: Australian Citizen

Inventor's Signature: _____ Date: 16/2/05
(if not contained in the request, or if declaration is corrected or added under Rule 26*ter* after the filing of the international application. The signature must be that of the inventor, not that of the agent)

(of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26*ter* after the filing of the international application)

☐ This declaration is continued on the following sheet, "Continuation of Box No. VIII (iv)".